Remarks

Claims 1-16 are pending in the subject application. By this Amendment, Applicants have amended claims 1 and 9 and added new claims 17-26. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-26 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The specification has been objected because it contains embedded hyperlinks or other forms of browser executable code and because of an informality. The specification has been amended to correct an inadvertent typographical error in the recitation of "122" amino acids at page 280, line 28, to "112." As the Patent Office is aware, an amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 U.S.P.Q. 268 (C.C.P.A. 1971). Applicants respectfully submit that the amendment to the specification does not constitute new matter as it would be clear from the comparison of the claimed sequence with that of the Trembl ID: Q9UGZ4 (as discussed in the specification at page 280, lines 20-29) that the N-terminal 112 amino acids were identical and the remaining 22 amino acids of the claimed sequence differed from that of Trembl ID: Q9UGZ4. Accordingly, Applicants respectfully submit that these issues are moot in view of the amendments made to the specification and withdrawal of the objections to the disclosure is respectfully requested.

Claims 1-16 are rejected under 35 U.S.C. § 101 as not being supported by either a specific and substantial asserted utility or a well-established utility. The claims are also rejected under 35 U.S.C. § 112, first paragraph, on the basis that one skilled in the art would not k now how to use the claimed invention as there is no specific and substantial asserted utility or a well-established utility for the claimed invention. Relying on Kedra *et al.* (*Human Genetics*, 1998, Vol. 103, pp. 131, 141), the Office Action asserts that the synaptogyrin splice variant of the present invention lacks two of the four transmembrane domains that are characteristic of the members of the synaptogyrin family. The Office Action further asserts that it is not clear whether the splice variant of the present invention is functional and notes that the function of the claimed polypeptide has not been "demonstrated in the

specification". On this basis, the Office Action rejects claims 1-16 as not being supported by either a specific and substantial asserted utility or a well-established utility.

At the outset, Applicants respectfully submit that the patent laws contain no requirement for demonstrating the function of a claimed product in the specification of a patent application. Indeed, working examples are not required in a patent application. *See In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962). Thus, it is respectfully submitted that the utility of the claimed invention does not turn on whether its function has been "demonstrated in the specification". Rather, the test is whether it is more likely than not that the claimed polypeptide has the functions asserted in the specification and can be used for the purposes set forth therein.

Applicants respectfully submit that the tridimensional structure of a member of the synaptogyrin family has only been established for rat SYNGR1, which corresponds to human synaptogyrin 1a (see Kedra *et al.*, page 138, right column, lines 7-11). Thus, in view of Kedra *et al.*, it can only be concluded that rat synaptogryin spans the membrane four times. For human synaptogyrins, the structure is only based on a prediction using the PredictProtein program (see page 138, right column, lines 11-14 of Kedra *et al.*). However, the accuracy of this prediction cannot be ascertained. For example, using another prediction program, *i.e.*, the TMHMM program, human synaptogyrin 1c of Kedra *et al.* is predicted to span the membrane three times and not the four times predicted by Kedra *et al.* using PredictProtein (see Appendix 1 attached herewith). Thus, Applicants respectfully submit that a synaptogyrin splice variant taught to span the membrane two times does not allow for the conclusion that a splice variant is not a functional synaptogyrin simply in view of Kedra *et al.* and the arguments set forth in the Office Action.

In addition, as shown on the attached Appendix 2, the synaptogyrin splice variant of the present invention displays many characteristic features that are common to all members of the synaptogyrin family and previously noted in the Office Action at page 3. For example, the presently claimed polypeptide exhibits:

1. The central conserved domain identified in Kedra *et al.* (see sentence bridging pages 137-138 in Kedra *et al.*). This conserved domain is indicated by "*" in Appendix 2 (appended hereto);

2. The strong conservation among the first 16 amino acids residues between rat synaptogyrin and human synaptogyrin 1a and 1b (see page 138, left column, lines 6-9 of Kedra *et al.*). These 16 amino acids are indicated by "+" in Appendix 2;
3. Outside of the above-described central and N-terminal portions of the polypeptide, a C-terminal variable end that is likely to convey the functional specificity of each protein (see page 138, right column, lines 2-5 of Kedra *et al.*). This variable portion of the synaptogyrin of the present invention is highlighted in grey in Appendix 2; and
4. Two cysteines present between the first and the second transmembrane domains of rat synaptogyrin that form a disulfide bond (see page 138, right column, lines 17-20 of Kedra *et al.*). These cysteines are highlighted by boxes in Appendix 2.

In view of the above, it is respectfully submitted that one of skill in the art would conclude that it is more likely than not that the synaptogyrin splice variant of the present invention is a functional synaptogyrin, particularly in view of Kedra *et al.*

Applicants also respectfully submit that one skilled in the art would have known how to use the claimed invention in view of the teachings of the specification. Particularly, one skilled in the art would have been able to use the claimed polypeptide for purposes such as marker protein (*e.g.*, fused to a tag such as FLAG or another tag; see, for example, specification at page 62, lines 8-12) to identify secretory and endocytic traffic in cells (specification at page 282, lines 15-16). Alternatively, one skilled in the art would have also been able to use the claimed polypeptide for targeting of heterologous polypeptides or polynucleotides to components of the secretory machinery (specification at page 282, lines 24-27). In view of the foregoing analysis, Applicants respectfully submit that one skilled in the art would have concluded that the claimed polypeptide could be used as asserted in the specification and that any number of utilities asserted in the specification were credible, specific, and substantial utilities (*e.g.*, as research tools/marker proteins for identifying secretory and/or secretory traffic in vesicles). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §§ 101 and 112, first paragraph, is respectfully requested.

Claims 1-5, 7, 9-13, and 15 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession

of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention and that the claims are enabled by the subject specification. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) the court explained further that the written description requirement may be satisfied "if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." As indicated in the as-filed specification, a 134 amino acid splice variant of synaptogyrin (SEQ ID NO: 297) is taught. Additionally, the first 112 amino acids of the claimed polypeptide are identical to synaptogyrin 1 (TREMBL: Q9UGZ4) and the specification discloses various domains of the claimed polypeptide (*e.g.*, transmembrane domains, *etc.*). Indeed, the as-filed specification indicates that the claimed polypeptide "presents the same N-terminal domain (which is highly conserved in all synaptogyrins)" (see page 280, line 30). Thus, the as-filed specification teaches the particular structure of the claimed polypeptides as well as various domains identified within SEQ ID NO: 297. As noted above, Kedra *et al.* disclose a number of highly conserved regions among the synaptogyrins (see paragraph bridging columns 1-2, page 138). For example, the first 16 amino acids of rat mouse and human synaptogyrin 1 (a and b forms) and synaptogyrin 2 show strong conservation. Additionally, the first 33 amino acids of three orthologous proteins (human SYNGR1a, RATSYNGR1a and mouse Syngr1b) are identical. Applicants submit that no more than about six to seven amino acid changes are embraced by the claims and those skilled in the art would have recognized those domains in which substitutions would be tolerated without adversely affecting the biological function of the claimed polypeptide (*e.g.*, conservative amino acid substitutions, as set forth at page 64, lines 23-26, in transmembrane domains) and those domains in which no substitutions should be made (*e.g.*, amino acids 1-16 or 1-33, highly conserved amino acids among the members of the synaptogyrin family). In view of such facts, it is respectfully submitted that the claimed invention satisfies the written description requirement, and reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 3 and 11 are rejected under 35 U.S.C. § 112, first paragraph as nonenabled by the subject specification. Applicants respectfully assert that the claims are enabled. However, in an effort to expedite prosecution, Applicants' undersigned representative hereby submits a deposit

declaration indicating that the deposited material, *Escherichia coli* DH10B GENSET.071PRF was accepted for deposit at the American Type Culture Collection on February 1, 2000 (ATCC Designation No. PTA-1218) under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure (*e.g.*, see 961 OG 21, 1977) and that all restrictions on the availability to the public of the materials so deposited will be irrevocably removed upon the granting of a patent disclosing the deposit. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

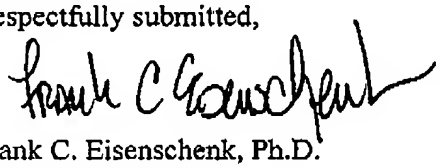
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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FCE/gyl/sl
Attachments: Appendix 1
Appendix 2
Declaration of Frank C. Eisenschenk, Ph.D.

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